Telephone Log
April 6, 2005

Name: Cazemiro R. Martin	Position: Regulatory Review Chemist/IDS
Company Name: **Lorna C. Totman, Ph.D., Senior Director of Scientific Affairs and Toxicology, Consumer Healthcare Products Association (CHPA)**	Drug / Ingredient Name: Carbaspirin calcium and Choline salicylate
Nature of Call: Indicate to CHPA that there are no United States Pharmacopeia (USP) monographs for carbaspirin calcium and choline salicylate.	

IND or NDA Number / Monograph Issue:

IND No:	NDA No:	Monograph Issue: There are no USP monographs for carbaspirin calcium and choline salicylate. Before these ingredients can be included in the OTC analgesic final monograph, USP monographs must be established for each of these ingredients.

Phone Number **(202-429-9260)**	Fax Number

Nature of Call

	FR Request		Agendas/Meetings		Consumer Complaint		Fax No./Address Req.
	Milestone List		Speeches (Copies)		Product Information		DODE Responsible List
	RX/OTC Switch List	X	Feedback Information		Press Office/Backgr'd		
	Ingredient List		Document Status		Consult/Advise		
X	Ingredient Information		Status of Submission		Labeling Information		

Memo of Phone Call:

Call Placed By: Cazemiro R. Martin	Time: Approx. 11:15 a.m.	File: teloCHPA.doc

Background:

Agency policy requires that all OTC drug monograph ingredients be listed in the United States Pharmacopeia (USP). Carbaspirin calcium and choline salicylate, category I ingredients in the OTC internal analgesic tentative final monograph (53 FR 46204; November 16, 1988), are not currently listed in the USP.

Discussion:

On April 6, 2005, Mr. Martin called Dr. Lorna Totman of CHPA to indicate that there are no USP monographs listed for either carbaspirin calcium and choline salicylate. Mr. Martin pointed out that in a letter dated Mary 17, 1994, from Michael Kennedy of FDA to Mr. Cope of CHPA (formerly NDMA), FDA informed the association that USP monographs need to be established for several ingredients, including OTC internal analgesic active ingredients

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carbaspirin calcium and choline salicylate. In that letter, FDA indicated that these ingredients would not be included in an OTC final monograph unless publicly available chemical standards are developed (i.e., USP monograph). Mr. Martin also stated that the OTC internal analgesic final monograph is being developed and therefore, only those active ingredients listed in the USP will be considered for inclusion in the final rule.

Dr. Totman indicated that she would determine if there are OTC drug products currently marketed with these two ingredients or if members of CHPA intend to market such products with these ingredients in the future. She also indicated that if CHPA determines that there are such OTC analgesic products with these ingredients or may be in the future, the Association will assist USP to establish monographs as soon as possible.

Dr. Totman thanked Mr. Martin for bringing this issue to her attention.

Cazemiro R. Martin
Reg. Review Scientist/IDS

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cc: Docket Nos. 1977N-0094 and 1977N-094I
HFD-560: OTC Internal Analgesic
HFD-560: SJohnson/GRachanow/MChang/CMartin/EAbraham
4/7/05: To Division of Dockets Management

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: April 7, 2005

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 1977N-0094 and 1977N-094I

TO: Dockets Management Branch, HFA-305

☑ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment